Amendments to the Specification

Please amend paragraph 013 as follows:

The present invention is directed to processes and apparatus for making an implant comprising soft tissue more suitable for implantation into a recipient. Soft tissues (such as tendons and ligaments) treated according to the present techniques are wholly or partially passivated by contact with cleaning agents, such as a solution containing **[[a]]** **an** oxidizing sterilant (for example, hydrogen peroxide). The tissues are protected from damage from the oxidizing sterilant by contacting the tissues with a protective agent, such as an alcohol, and/or by application of kinematic restraint, such as tension. Those soft tissues tend to have superior structural, mechanical, and/or biochemical integrity and experience less collagen damage attributable to such contact with the oxidizing sterilant. Indeed, the application of tension to the implant while it is contacted with cleaning agents (such as a detergent, an alcohol, or a peroxide) can reduce the damage attributable to the cleaning agents.

Please amend paragraph 041 as follows:

Kinematic restraint, as used herein, refers to control over the physical position and/or orientation of the implant and may ~~**including**~~ **include** tension, compression and/or immobilization of the implant or any specific portions of the implant. Preferably, the kinematic restraint applied to the implant comprises tension applied to the soft tissue of the implant. Suitable kinematic restraint apparatus may provide axial and/or radial restraint or tension to an implant or provide tension or restraint to an implant in one, two or three dimensions. Kinematic restraint applied to an implant may include tension, compression, or immobilization applied to the implant, preferably to the soft tissue of an implant. Kinematic restraint provides control of position, orientation, motion, or stresses of the implant comprising the soft tissue in from 1 to 6 degrees of freedom.

Please amend paragraph 049 as follows:

The present processes may be used in conjunction with other techniques for reducing the likelihood of providing implants having undesirable components therein. For example, methods for minimizing the risk that pathogenic donor tissue will be harvested and processed by a tissue bank, referred to herein as donor qualification, are known in the art. Accordingly, thorough donor screening, and tissue testing by enzymatic, immunological, biochemical and molecular biological techniques are applied to minimize the risk that tissue carrying pathogens (viruses, bacteria, and the like) will be included in the materials processed and made available for implantation. Testing for contamination by human immunodeficiency virus, HIV, hepatitis B virus, HBV, hepatitis C virus, HCV, has now become routine in the art. Known screening and qualification methods are desirably included as an initial step preceding processing of the implant material according to the present processes. None of these screening methods are 100% percent reliable, however, as is evidenced by recent cases involving allograft disease transmission. *Morbidity and Mortality Weekly Report,* U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, December 5, 2003 ("Although allograft infections are rare, they highlight the need for improved tissue evaluation and processing standards."). Due to the highly efficient implant treatment processes disclosed herein**, it [[. It]]** is further expected that as yet unidentified potentially pathogenic organisms or organisms for which routine testing has yet to be developed may be removed from implants by virtue of the present treatment processes. Redundancy in the level of implant cleaning that is built into the present passivation processes ensures removal and inactivation of such organisms or potentially pathogenic factors while at the same time permitting efficient implant processing.

Please amend paragraph 058 as follows:

Preferably, the cleaning agent is made to perfuse the implant by use of cycling pressure in a sufficient number of cycles. The number of ~~rinse~~ cycles may be from 1-150 times, preferably about 1-50 times, more preferably about 5-10 times. Suitable cyclically increased and decreased pressures are set forth above. Suitable temperatures at which the cleaning agent is contacted depend in part on the cleaning agent and its concentration, but desired temperatures include at least about 30°C, alternatively at least about 40°C, alternatively at least about 42°C, alternatively at least about 48°C. When the cleaning agent comprises a relatively high concentration of alcohol, it may be desirable to employ lower temperature, for example, about 35°C, about 30°C, about 25°C or even lower. The cleaning agent (other than the oxidizing sterilant) can be contacted with the implant for a suitable time period, for example from about 1 minute to about 120 minutes, alternatively from about 5 minutes to about 20 minutes, alternatively about 10 minutes. The foregoing time periods may be consecutive minutes, or they may be partitioned or separated by time periods where the implant is contacted with other cleaning agents, rinsing fluids, or other solutions.

Please amend paragraph 061 as follows:

Suitable alcohols for use in the present processes include methanol, ethanol, propanol (including isopropanol), and butanol (including isobutanol and tert-butyl alcohol). Isopropanol is presently preferred. The alcohol may be provided in a solution or mixture, with preferred ~~concentration~~ **concentrations** ranging from about 0.1% to about 100%, alternatively from about 5% to about 95%, alternatively from about 10% to about 80%. It is contemplated that the concentration of alcohol in an earlier contact step may be higher than the concentration in later contact steps. Preferred alcohols are those having low molecular weights (for example, in the range of from about 32 g/mole to about 360 g/mole, alternatively alcohols having molecular weights equal to or less than about 61 g/mole, alternatively about 90 g/mole, alternatively about 120 g/mole,

alternatively about 240 g/mole, alternatively about 360 g/mole) and/or melting points below the operating conditions of the embodiment being used of the present processes. It is contemplated that other protective agents might be used in place of alcohols, for example polyols. Preferred polyols are those having relatively low molecular weights (for example, in the range of from about 32 g/mole to about 360 g/mole).

Please amend paragraph 063 as follows:

Suitable rinsing fluids for use after contacting the implant with the oxidizing sterilant include alcohols, polyols (for example, glycerol), acetone, saline solutions, water, and mixtures thereof. The rinsing fluid can be provided as an aqueous solution. Aqueous solutions containing ~~nonohydric~~ **monohydric** alcohols having one to eight carbon atoms are presently preferred for use as the rinsing fluid.

Please amend paragraph 075 as follows:

The present processes and apparatus may reduce, minimize or eliminate one or more of the foregoing problems. By applying tension to an implant comprising a soft tissue during a treatment process employing cleaning agents, the positioning of the soft tissue in the chamber can be maintained in a desired fashion, and the cleaning agents are unlikely to be applied with enough force to change the positioning. Because cleaning agents contact the implants (particularly the soft tissue) more uniformly and predictably, there will be more consistency between different implants and within a single implant. Soft tissues will have less tendency to shrivel, and as a result there will be less likelihood of generating implants having undesirable appearance. By applying tension to a soft tissue during a treatment process, inflammation and damage from internal foaming reactions can be reduced, because there is greater opportunity for the foaming action to exit the stretched tissue, rather **than** remain inside the tissue to cause

more damage. Additionally, the tension applied during processing will protect the graft from post surgical laxity which can be caused by shrinkage and shriveling of the graft during conventional processing.

Please amend paragraph 0122 as follows:

Soft tissue samples were exposed to peroxide either for a continuous treatment or for a partitioned treatment, in which peroxide exposure was partitioned by alcohol washes. In both the continuous treatment and the partitioned treatment, the cumulative time of peroxide exposure was the same. Additionally, two different cumulative times of exposure **were** evaluated, one that was higher than the degradation time and one that was lower than the degradation time. Collagen levels were compared for all the samples.

Please amend paragraph 0125 as follows:

This example assesses the passivating effect of partitioned treatment and the reduction in collagen damage to tensioned tissues. This example also assesses the effects of applying tension to the samples during the partitioned treatment. Tendon samples from 3 different donors were provided. Samples to be evaluated for the passivating **effect** of the process were spiked with spores of *Bacillus stearothermophilus*. All the samples were exposed to peroxide for 60 cumulative minutes. Before the first peroxide exposure, and after each period of 20 consecutive minutes of peroxide exposure, the samples were contacted with an isopropanol solution.